

Subpart D—Cardiovascular Prosthetic Devices

§ 870.3250 Vascular clip.

(a) *Identification.* A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels other than intracranial vessels.

(b) *Classification.* Class II (performance standards).

§ 870.3260 Vena cava clip.

(a) *Identification.* A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

(b) *Classification.* Class II (performance standards).

§ 870.3300 Arterial embolization device.

(a) *Identification.* An arterial embolization device is an intravascular implanted device used to control internal hemorrhage or to halt blood flow in arteries supplying blood to certain types of abdominal tumors (e.g., nephroma, hepatoma) and arteriovenous malformations. This device is not used in intracranial arteries.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

§ 870.3375 Cardiovascular intravascular filter.

(a) *Identification.* A cardiovascular intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.

(b) *Classification.* Class II. The special controls for this device are:

(1) “Use of International Standards Organization’s ISO 10993 ‘Biological

Evaluation of Medical Devices Part I: Evaluation and Testing,’ ” and

(2) FDA’s:

(i) “510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)” and

(ii) “Guidance for Cardiovascular Intravascular Filter 510(k) Submissions.”

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 870.3450 Vascular graft prosthesis.

(a) *Identification.* A vascular graft prosthesis is an implanted device intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access. It is commonly constructed of materials such as polyethylene terephthalate and polytetrafluoroethylene, and it may be coated with a biological coating, such as albumin or collagen, or a synthetic coating, such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance Document for Vascular Prostheses 510(k) Submissions.”

[66 FR 18542, Apr. 10, 2001]

§ 870.3470 Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.

(a) *Identification.* An intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

(b) *Classification.* Class II (performance standards).

§ 870.3535 Intra-aortic balloon and control system

(a) *Identification.* A intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and